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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|---|-------------|----------------------|-----------------------------|------------------------|
| 10/659,755  | 09/10/2003  | Richard A. Dixon     | NBLE:007US                  | 4103                   |
| 32425 7590 07/30/2007<br>FULBRIGHT & JAWORSKI L.L.P.<br>600 CONGRESS AVE.<br>SUITE 2400<br>AUSTIN, TX 78701 |             |                      | EXAMINER<br>KALLIS, RUSSELL |                        |
|   |             |                      | ART UNIT<br>1638            | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>07/30/2007     | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/659,755

Applicant(s)

DIXON ET AL.

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-35 and 46-50 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 36-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-35 and 46-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/03;11/04;6/05;12/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

Claims 1-50 are pending. Claims 1 and 36-45 are withdrawn. Claims 2-35 and 46-50 are examined.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Wisman *et al.* PNAS, Oct. 1998, Vol. 95, pp. 12432-12437.

The claim is broadly drawn to a plant having a loss of function mutant for a flavanone 3-hydroxylase gene.

Wisman teaches a *tt6* mutant in *Arabidopsis* wherein the *tt6* gene comprises a mutant flavanone 3-hydroxylase that has lost its' function of converting its' substrate into product thereby allowing for the accumulation of naringenin (i.e. the substrate of the flavanone 3-hydroxylase) which is also the substrate of isoflavone synthase (see page 12,435 in figure 3 part A); and thus the reference teaches all the limitations of claim 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-35 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,189,895 (McGonigle, B. and Odell, J.) with the effective filing date of June 13, 2002 (60/388,280) in view of U.S. Patent 7,098,011 published August 3<sup>rd</sup>, 2000 as WO 00/44909; and in further view of Applicant's disclosure of the state of the prior art.

The claims are broadly drawn to a method of increasing isoflavonoid biosynthesis in a plant by down regulating flavanone 3-hydroxylase and upregulating expression of isoflavone synthase and chalcone isomerase and plants transformed thereby.

Patent 7,189,895 teaches a method of increasing isoflavonoid biosynthesis in a plant by down regulating flavanone 3-hydroxylase and up-regulating expression of isoflavone synthase and chalcone isomerase by transformation with maize C1 and R transcription factors in conjunction with an antisense flavanone 3-hydroxylase and plants transformed thereby (see ); and that the C1 and R transcription factors upregulate expression of chalcone synthase and chalcone isomerase as well as the expression of other enzymes of the phenylpropanoid pathway in plants (see column 2 to the end of section in column 3; also incorporated through reference WO 00/44909 presented supra as U.S. Patent 7,098,011 (see column 3 lines 30-60; and column 21 lines 59 to end of paragraph); and the abstract and claims of both patents).

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Applicant's disclosure teaches that the instantly claimed sequences were taught in the art (see specification pages 14-15 flavanone 3-hydroxylase SEQ ID NO: 10, 13, 15; page 45 chalcone isomerase SEQ ID NO: 3; page 43 for isoflavone synthase i.e. SEQ ID NO: 1; and McKhann and Hirsh, 1994 from Applicant's IDS for SEQ ID NO: 5 and 6).

It would have been obvious at the time of filing for one of ordinary skill in the art to increase isoflavone synthase in any plant by down regulating flavanone 3-hydroxylase and up-regulating expression of isoflavone synthase and chalcone isomerase by substituting specific genes encoding chalcone synthase and chalcone isomerase for the transcription factors C1 and R that up-regulate the phenylpropanoid pathway. One would have been motivated by the teachings of U.S. Patent 7, 098,011 and 7,189,895 that chalcone synthase and chalcone isomerase are the penultimate and last steps leading to the synthesis of naringenin the substrate for isoflavone synthase and could reproduce the upregulation of the pathway achieved by using the transcription factors C1 and R and that inhibiting flavanone 3-hydroxylase would reduce or eliminate competition between flavanone 3-hydroxylase and isoflavone synthase for naringenin (see figure 1 in either patent); and had a reasonable expectation of success patent 7,189,895 (see column 24-25) and patent 7,098,011 (see column 42 Table 5 and columns 46-47 in analysis of transformed soybean embryos).

All claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.  
July 16, 2007

RUSSELL P. KALLIS, PH.D.  
PRIMARY EXAMINER

*Russell Kallis*